MAY 2 7 2011

Attachment C2

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: k102049

1. Submitter's Identification:

TaiDoc Technology Corporation
3F, 5F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan

Correspondent:
Teling Hsu
Regulatory Affairs Specialist
Tel: +886-2-6625-8188 #1176
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Email: teling.hsu@taidoc.com.tw

Prepared date: July 21, 2010

2. Device name:

Proprietary name: Clever Choice Voice + Blood Glucose Monitoring System, model TD-4248

Regulatory information:

A. Regulation section: 21 CFR 862.1345 Glucose Test System
B. Classification: Class II
C. Product Code: CGA, Glucose Oxidase, Glucose
NBW, System, Test, Blood Glucose, Over The Counter
D. Panel: Clinical Chemistry (75)

3. Intended Use:

The Clever Choice Voice + Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative site testing in this system can be used only during steady-state blood glucose conditions.

The Clever Choice Voice + Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system contains a speaking functionality which provides step by step instructions to aid visually impaired persons.

4. Device Description:

The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only Clever Choice Voice+ Test Strips with the Clever Choice Voice + Blood Glucose Monitoring System.

5. Substantial Equivalence Information:

   A. Predicate device name: FORA V20 Blood Glucose Monitoring System
   B. Predicate K number: K100406
   C. Comparison with predicate:

The modified Clever Choice Voice + Blood Glucose Monitoring System has the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life

- packaged using the same materials, and
- manufactured by the same process.

The modifications encompass:

- Meter outer casing design change, such as color and printing,
- Software modification of language spoken by meter only in English,
- Software modification of selectable blood glucose measurement unit (mg/dL or mmol/L) and use mg/dL as the preset unit.

6. Test Principle:
   The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose oxidase.

7. Performance Characteristics:
   Clever Choice Voice + Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

   A comparison of system accuracy performance demonstrated that the Clever Choice Voice + Blood Glucose Monitoring System and the FORA V20 Blood Glucose Monitoring System are substantially equivalent.

   Software verification and validation testing confirmed that the performance, safety and effectiveness of the Clever Choice Voice + Blood Glucose Monitoring System are equivalent to the predicate device.

8. Conclusion:
   Based on the information provided in this submission, the Clever Choice Voice + Blood Glucose Monitoring System is substantially equivalent to the predicate FORA V20 Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

MAY 27 2011

TaiDoc Technology Corporation
c/o Teling Hsu
3F, 5F No.127, Wugong 2nd Road, Wugu Township
Taipei County
China (Taiwan) 24888

Re: k102049
Trade/Device Name: Clever Choice Voice+ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: February 25, 2011
Received: May 16, 2011

Dear Ms. Hsu

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment C1

Indications for Use

510(k) Number (if known): k102049

Device Name:
Clever Choice Voice + Blood Glucose Monitoring System, model TD-4248

Indications for Use:
The Clever Choice Voice + Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative site testing in this system can be used only during steady-state blood glucose conditions.

The Clever Choice Voice+ Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system contains a speaking functionality which provides step by step instructions to aid visually impaired persons.

Prescription Use _____	AND/OR	Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K102049